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10/720,985	11/24/2003	Peter Michel	14306.01	3362
7590 10/31/2007				
David E. Bruhn		EXAMINER		
DORSEY & WHITNEY LLP		BHATIA, AARTI		
Intellectual Property Department, Suite 1500				
50 South Sixth Street		ART UNIT		
Minneapolis, MN 55402-1498		PAPER NUMBER		
		4123		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/720,985

Applicant(s)

MICHEL, PETER

Examiner

Aarti Bhatia

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-48 is/are pending in the application.
- 4a) Of the above claim(s) 13-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 40-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 13-48 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/077,229.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 13-39, drawn to an injecting device, classified in class 206, subclass 365 .
- II. Claims 40-48, drawn to a method of injecting, classified in class 604 , subclass 131.

1. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of injecting does not require a device with an ampoule or reflux valve.

2. During a telephone conversation with David Bruhn on October 3, 2007, a provisional election was made without traverse to prosecute the invention of group 2, claims 40-48, drawn to a method of injecting. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 40-44, and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (US Patent 5,788,673).

With respect to claim 40, Young et al teach a first volume (figure 2, (162)), and a second volume (figure 2, (164)), wherein the volumes are adapted to contain a fluid (figure 2, (166)), placing the volumes in fluid communication (figure 2, (172) and column 8, lines 27-30), fluid medium can be passed from chamber 162 (thereby decreasing the volume of the first volume) into chamber 164 (thereby causing the amount of fluid in the second volume to increase) (column 8, lines 28-30), which increases the volume of the second volume and causes the administration of injectable product from the reservoir (column 8, lines 60-63).

With respect to claim 41, Young et al teach that the fluid is a liquid (abstract, line 25).

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With respect to claim 42, Young et al teach that the first volume is decreased by urging a first piston (figure 3, (156)), against the first volume (column 8, lines 19-22).

With respect to claim 43, Young et al teach that a spring (figure 3, (176)) urges the first piston (column 7, lines 7-8).

With respect to claim 44, Young et al teach that the increasing second volume (figure 5, (164)), acts against a second piston (figure 5, (152); column 6, lines 25-26). Once the volume is transferred from chamber 162 to chamber 164, the increased volume of 164 causes piston 152 to move forward (column 8, lines 60-63).

With respect to claim 46, Young et al teach that the second piston (figure 5, (152)), has a piston rod (figure 5, (154)), operably coupled to a third piston (figure 5, (26)) 26 represents the plunger of syringe 22, displaceable through the reservoir (figure 5, (24)), and in contact with the injectable product. The present application teaches that the third piston can be any delivering means suitable for delivering the product, the plunger of Young et al fulfills this requirement.

With respect to claim 47, Young et al inherently teach a pressure differential between the first volume and the second volume when the first volume is being decreased, since there needs to be a pressure differential for the fluid to move from one volume to the other.

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With respect to claim 48, Young et al teach an injection pen or syringe casing generally enclosing said volumes (figure 1, (121); column 5, lines 50-55).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Tountas (US Patent 4,773,419).

Young et al fail to describe the contact area between the piston and the fluid.

Tountas teaches that the piston area in an injection device is related to the pressure that it generates (column 4, lines 40-45). Young et al show a piston area 156 in contact with fluid 166 in volume 162. It is inherent from Young et al that the force of

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the first volume is greater than that of the second volume since the force of the first piston 156 on the first volume 162 is what drives the second volume 164 to act on the second piston 152. It would have been obvious to include different piston areas so that the area of contact between the first piston and the fluid in the first volume is larger than an area of contact between the second piston and the fluid in the second volume, to generate different pressures. This would achieve the result of Young et al., whereby the force of the first piston on the first volume acts to increase the second volume, which then acts on the second piston to drive a third piston to deliver the injectable product.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am -6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB

  
JOSEPH DEL SOLE  
SUPERVISORY PATENT EXAMINER  
10/30/07